MAR 1 6 2012

Exhibit #1

510(k) SUMMARY

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K111541.

1. Submitter's Identification:

Essential Dental Systems
89 Leuning Street
South Hackensack, NJ 07606

Date Summary Prepared: June 1st, 2011
Date Summary Revised: February 13th, 2012

Contact: Mr. Jeffrey Wan
Contact Phone #: 201-487-9090 ext. 118
Contact Fax #: 201-487-5120

2. Name of the Device:

Trade name: Endo-Express® Handpiece
Common name: dental handpiece
Classification name: dental handpiece (21 CFR 872.4200, Product Code EGS)

3. Predicate Device Information:

1. TEP E4R, K#962540, NSK Nakanishi, Tochigi, Japan

4. Device Description:

Endo-Express® Handpiece is a reciprocating handpiece for use with NiTi or stainless steel instruments during endodontic procedures. The handpiece is driven by an air motor. The steps required to properly operate the handpiece are: push button to open chuck, insert instrument handle into chuck, release button to close chuck, run handpiece. After use, the handpiece should be lubricated and autoclaved.

The contents of the kit are

1 – Endo-Express® Handpiece
1 – Lubricant bottle
1 – nozzle attachment

5. Intended Use:

Endo-Express® Handpiece is indicated for the removal of dentin, shaping and obturation of the root canal. This application area extends to endodontic procedures using NiTi or stainless steel endodontic instruments intended by the manufacturer for use in the mechanical preparation of root canals.

6. Comparison to Predicate Devices:

The subject device is similar to the TEP E4R in that they are both 90° reciprocating handpieces used in conjunction with various endodontic instrumentation systems for the treatment of root canals. The directions for use for these materials are nearly identical.

The subject device differs from the TEP E4R in cosmetic appearance and the max allowable motor speed.

Characteristic	Endo-Express®	TEP E4R
Max Motor Speed	12,000min^{-1}	40,000min^{-1}
Latch Type	Push Button Chuck	Push Button Chuck
File Type	hand files	hand files
Motor Connection	E-Type air or electric motor	E-Type air or electric motor
Reduction Ratio	4:1	4:1

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:

Not Applicable

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

Endo-Express® Handpiece has the same intended use and similar technological characteristics as the predicate device. Thus, Endo-Express® Handpiece is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jeffrey Wan
Research and Development Manager
Essential Dental Systems, Incorporated
89 Leuning Street, Suite 8
South Hackensack, New Jersey 07606

MAR 16 2012

Re: K111541
Trade/Device Name: Endo Express® Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: March 7, 2012
Received: March 8, 2012

Dear Mr. Wan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): K111541

Device Name: Endo Express® Handpiece

Indications for Use:

Endo-Express® Handpiece is indicated for the removal of dentin, shaping and obturation of the root canal. This application area extends to endodontic procedures using NiTi or stainless steel endodontic instruments intended by the manufacturer for use in the mechanical preparation of root canals.

Prescription Use X (Per 21 CFR 801 Subpart D) **OR** **Over the Counter Use** ____ (Per 21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111541